

Office of Research Oversight (ORO) Guidance Regarding Research Compliance Officer (RCO) Audit and Training Requirements for the June 1, 2021 - May 31, 2022 Reporting Period

1. **RCO audit requirements.** This guidance clarifies and supersedes previous guidance on the requirements for RCO informed consent audits and protocol regulatory audits and applies to the June 1, 2021 - May 31, 2022 reporting period. ORO provides audit tools on our website and the RCO section of the ORO SharePoint site. These tools are provided as examples; you are NOT required to use these specific forms or format. However, you must include, at a minimum, all the required information in the audit tools.
 - a. **Definition of RCO audit.** RCO audits are audits **conducted, supervised, or verified** by the facility's lead RCO.
 - b. **Definition of active study.** An “active” study is a study approved by and under continuing oversight from the Research and Development Committee (R&DC), Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Subcommittee on Research Safety (SRS), or other VA or VA-designated research oversight committee, regardless of whether the study is “open” or “closed” to accrual.
 - c. **Definition of completed study.** A “completed” study is a study for which oversight by all relevant research oversight committees (see Item 1.b above) has been concluded.
 - d. **Definition of Informed Consent Documents (ICDs) to be audited.** The RCO informed consent document (ICD) audit requirement refers to the research ICDs required under 38 CFR 16.116 and 16.117 (and VHA Directive 1200.05 §§17 through 18). Re-consents for research should also be audited and counted as a separate consent. Regardless of how research protocols and parts of research protocols are tracked or labeled by an IRB or cooperative group, “sub-studies” also constitute research that requires specific IRB approval of the “sub-study” protocol and informed consent, and RCOs are required to audit those sub-studies, and ICDs as described above. Each ICD should have a separate line on the RCO's audit tool. For purposes of counting for the FDC, each ICD audited should be counted separately- even if multiple ICDs applied to the same individual.

Consent forms that are required by VHA policy outside of the requirements of 38 CFR 16.116 and 16.117 (and VHA Directive 1200.05) are NOT required to be audited by RCOs, unless required by local facility standard operating procedures. Consents for medical procedures and consents for photography and voice recording are examples among others that are not required by ORO guidance to be audited.

2. **Informed consent audits.** Informed consent audits of all **active human** research studies must be performed **each year** (i.e., annually, during the June 1- May 31 reporting period) and require in every case a confirmation of the administrative data on the ORO informed consent audit tool, the most recent continuing review by the IRB or R&DC, as well as a review of subjects' signed VA informed consent documents, where applicable, and HIPAA authorization documents, where applicable.

- a. **Studies to be audited.** All human research studies **active at any time** during the reporting period must receive an informed consent audit, whether or not any ICDs were required or signed during the reporting period. Human subjects studies that no longer require continuing IRB review must be audited yearly as they are still under the oversight of the IRB.
- b. **IRB-exempt studies.** The annual informed consent audit requirement includes human studies determined to be exempt from IRB review. The audit requirement for exempt human research is fulfilled by completing or re-confirming the administrative data section of the ORO informed consent audit tool (or locally-modified equivalent). The box for “Exempt” should be checked, and the auditor should confirm that the R&DC has performed initial and/or continuing reviews as required by VA policy for any active study that is not followed by any other research oversight committee.
- c. **Studies overseen by the IRB with no ICDs signed during this period.**
If an active human study has no ICDs signed during the period being audited, the audit requirement is fulfilled by completing or re-confirming the administrative data section of the ORO informed consent audit tool (or locally-modified equivalent). The reason there are no ICDs to audit should be noted. This may be because informed consent was waived by the IRB, or the documentation of informed consent was waived by the IRB, or because ICDs were approved but no subjects were accrued (including screen fails) or re-consented during the period being audited. The auditor should also note whether continuing review of the study occurred as required by VA policy.
- d. **ICDs to be audited.**
 - i. Initial audits of studies must include all ICDs and HIPAA authorizations (as required) obtained since study initiation. Studies initiated during this period must have an informed consent audit during this period even if consent has not yet been obtained from any subjects.
 - ii. For current studies in which ICDs and HIPAA authorizations were audited in the previous cycle, the RCO must audit all new ICDs and HIPAA authorizations obtained since the previous audit. This includes re-consents, if any.
 - iii. If either HIPAA authorization or documentation of informed consent, but not both, has been waived by the IRB, the document that is not waived must be audited.
 - iv. Special guidance applies to auditing of ICDs and HIPAA authorizations for the Million Veteran Program. See “*ORO Requirements for RCO auditing of Informed Consent and HIPAA Authorization forms for the Million Veteran Program Issued January 31, 2020*” posted on the RCO portion of the ORO SharePoint site.
- e. **Studies in Data Analysis or Long-Term Follow up.** Once a protocol has had at least one ICD audit, additional ICD audits are not required for studies that satisfy (i) or (ii) below:
 - i. Where 1) the research is permanently closed to the enrollment of new subjects; **and** 2) all subjects have completed all research-related interventions; **and** 3) the research remains active only for long-term follow-up of subjects; or
 - ii. The remaining research activities are limited to data analysis.

- f. **Studies completed during the reporting period.** An informed consent audit must be conducted for any active study that is completed during this period. If a study was previously audited during the reporting period, a supplemental IC audit should be completed before the end of the reporting period to capture any ICDs not previously audited prior to study completion. If no additional ICDs were obtained, then the audit already performed during the reporting period is sufficient and a supplemental audit is not required.
- g. **Records that will need to be reviewed** may include but not be limited to IRB regulatory files, versions of approved ICDs, and records that indicate all subjects who have signed informed consent documents.
- h. **Informed Consent Audit Plan or SOP** Each facility must have an audit plan or standard operating procedure (SOP) that describes the RCO's auditing process, including informed consent audits. The SOP or auditing plan should address the source records that may need to be reviewed for auditing purposes and the roles of the RCO, the PI, and others in the audit process. The plan or SOP should describe how human studies are planned for auditing during the year, how informed consent audits are scheduled and executed, how progress towards accomplishing all required audits is monitored, procedures for soliciting study investigators' responses to preliminary audit findings, and how the results of all informed consent audits, including audits with no findings or minor findings, are reported as required by VHA Directive 1058.01, including timelines. It is also good practice to describe the RCO's audit record format(s) (electronic and/or hard copies), the locations where RCO records are maintained, and how security of records is assured.

It is a good practice for the auditor to examine the estimated numbers of human research studies that will require informed consent audits at the beginning of the audit period, in order to plan a schedule to accomplish auditing requirements. If IC audits are performed once annually, then all ICDs and HIPAA authorizations signed since the previous audit should be audited. Alternatively, a method of continuous auditing of documents throughout the year soon after they are signed may be established and combined with an administrative review of the oversight status (first half-page of the ICD audit tool) for all human subjects protocols once a year. If a continuous method is used, the auditor must reconcile their list of audited ICDs with the PI at least annually to confirm that all signed ICDs have been received and audited.

- i. **Deadline.** Informed consent audits for the reporting period must be completed in time to be included in the 2022 Facility Director Certification of Research Oversight, which will have to be submitted to ORO no later than the determined deadline. The deadline for the 2022 Facility Director Certification will be no earlier than July 15, 2022.

3. **Complete regulatory audits not required for VA research overseen by the Research and Development Committee only:**

- a. Any VA research study that is overseen by the R&D Committee only and is not overseen by the IRB, IACUC, or SRS does not require a **regulatory** audit, except for exempt studies under the 2018 Common Rule. VA research followed by the R&D Committee only may include human research exempt from IRB oversight, and also any study that does not involve human subjects, live animals, or any hazards or safety concerns. Any VA research that is overseen by the IRB, the IACUC or the SRS should be audited with the relevant ORO regulatory audit tool as described below.

- b. Any human study determined to be exempt from IRB review and followed only by the R&DC does not require a regulatory audit, except for exempt studies under the 2018 Common Rule, which require a one-time completion of the administrative portion of the HRPP tool, as well as the STUDY STAFF QUALIFICATIONS AND TRAINING portion of the tool. In addition, informed consent audits of IRB-exempt studies are required annually per Items 2.a and 2.b.
 - c. If a study is approved by expedited review under the pre-2018 Common Rule and after January 21, 2019 the study transitions to the 2018 Common Rule and is determined to be exempt, the following regarding regulatory audit of this now-exempt study is required:
 - i. If the study had a full HRPP regulatory audit prior to transition, the study only needs to have a one-time limited/exempt HRPP audit after transition.
 - ii. If the study did not have a full HRPP regulatory audit prior to transition, the study needs to have a one-time full HRPP regulatory audit (look-back to study initiation) after transition.
4. **Regulatory audits required for research overseen by the IRB using ORO's Human Research Protection Program (HRPP) audit tool.** Except as noted in Item 4.d., regulatory audits of human research studies must be performed at least every 3 years (i.e., triennially). Initial audit with the HRPP tool must be no later than 3 years from initial approval as VA research by the R&D Committee. Subsequent audits with the HRPP tool (or local equivalent) must be completed no later than 3 years from the previous HRPP audit. Exceptions to the requirement for subsequent triennial audit are in 4 d.(iii) below.
- a. **HRPP audits required.** Except as noted in Item 4.d., all active human research studies overseen by the IRB must receive at least one HRPP audit. RCO auditors are allowed to add additional audit elements to ORO's HRPP audit tool and to reformat the data collection instrument, as long as audits include at a minimum all required information on the ORO HRPP audit tool.
 - b. **Records Reviewed** A complete HRPP audit must include a review of both the IRB study file and the Principal Investigator's records. Additional records to be reviewed may include, but not be limited to, case records, research personnel training records, and other research records.

ORO believes that a thorough HRPP regulatory audit requires a reasonable awareness of the goals and methods of the research, as well as the manner of obtaining and documenting informed consent. Therefore, when performing an HRPP regulatory audit, ORO expects the RCO auditor to achieve this awareness by reviewing the most recently approved informed consent document and HIPAA authorization, when required, and also to review relevant parts of the approved research protocol. The RCO auditor may also wish to enhance their understanding of the research by having a conversation with the PI and/or study coordinator. Please note that ORO does NOT expect the RCO auditor to read the entire protocol, nor to duplicate the work of the IRB, the scientific reviewers, the ISO or the PO. The RCO auditor should use professional judgment to determine when an adequate awareness, *sufficient for the purposes of conducting the HRPP regulatory audit*, has been achieved.

It is also important for the RCO auditing process to be transparent to the PI and study staff. Therefore, when performing audits, ORO expects the RCO auditor to explain the audit process in

an in-person conversation, by telephone, or to include this information in an explanatory email. At the conclusion of the record review the RCO auditor should review the preliminary findings with the PI/staff and clarify any questions or apparent deficiencies. In cases where the RCO does not feel that a conversation is necessary, the RCO should still make an offer to discuss the audit process and findings with the PI and/or study staff if they desire.

- c. **HRPP Audit Plan or SOP** Each facility must have an audit plan or standard operating procedure (SOP) that describes the RCO's auditing process, including HRPP regulatory audits. The SOP or auditing plan should address the source records that may need to be reviewed for HRPP auditing purposes and the roles of the RCO, the PI, and others in the audit process. The plan or SOP should describe how human studies are prioritized for auditing, how HRPP audits are scheduled and executed, how progress towards audit goals is monitored, procedures for soliciting study investigators' responses to preliminary audit findings, and how the results of all HRPP audits, including audits without any findings of reportable noncompliance, are reported to the IRB and R&DC as required by VHA Directive 1058.01, including timelines. It is also good practice to describe the RCO's audit record format(s) (electronic and/or hard copies), the locations where RCO records are maintained, and how security of records is assured.

It is a good practice for the auditor to examine the estimated numbers of human research studies that will require HRPP regulatory audits at the beginning of the audit period, in order to plan a monthly schedule to accomplish auditing requirements. ORO encourages RCOs to perform the first regulatory audit of newly-initiated VA research studies relatively early in the active research period.

- d. **Circumstances where HRPP audits are not required.** Regulatory HRPP audits of the following studies overseen by the IRB are not required, even at study closure:
 - i. **Human research followed by the IRB but initiated (i.e., approved for implementation by the R&DC as a VA study) prior to January 1, 2008 does NOT in most cases require a HRPP regulatory audit.** The exception to this "Grandfather rule" is that HRPP regulatory audits will now be required for studies that involve interaction or intervention with human subjects initially approved prior to January 1, 2008, and that remain open to enrollment.

Note: An initial HRPP regulatory audit for any such studies was required to have been performed in time to be reported on the 2014 Facility Director's Certification. Subsequent audits should be performed in accordance with the guidance in this section.

See ORO Guidance document "*MODIFIED AUDIT REQUIREMENTS FOR HUMAN SUBJECTS RESEARCH INITIALLY APPROVED PRIOR TO JANUARY 1, 2008*" dated November 15, 2012 available on the ORO website and Research Compliance and Technical Assistance SharePoint site.
 - ii. **Closure HRPP audits are not required after an initial HRPP audit.** Any human research protocol that has already had at least one HRPP regulatory audit and is completed or closed to oversight by the IRB less than 3 years after an HRPP audit does not require a final HRPP audit at closure. However, any research followed by the IRB that is closed to oversight by the IRB within less than 3 years must have at least one HRPP audit. If no HRPP audit has been done prior to closure by the IRB, then an HRPP audit must be done within the reporting period in which IRB oversight is completed.

- iii. **Repeat HRPP Audits for previously-audited research not required for certain studies.** Once a protocol has had at least one HRPP regulatory audit, additional HRPP regulatory audits are not required, even at study closure, for the following types of studies **determined by the IRB to involve no more than minimal risk**:
 - a. **Chart Review Studies.** Once a protocol has had at least one HRPP regulatory audit, additional HRPP regulatory audits are not required for studies solely involving chart reviews.
 - b. **Studies in Data Analysis and/or Long-Term Follow up.** Once a protocol has had at least one HRPP regulatory audit, additional HRPP regulatory audits are not required for studies **that satisfy (i) or (ii) below**:
 - i. Where 1) the research is permanently closed to the enrollment of new subjects; and 2) all subjects have completed all research-related interventions; and 3) the research remains active only for long-term follow-up of subjects; or
 - ii. The remaining research activities are limited to data analysis.
- iv. **Abbreviated HRPP audits.** If a human research study is opened and completed at a VA research facility without any research activity locally (enrolling any subjects or accessing any records) and before an HRPP audit is done, then the requirement for an HRPP audit may be satisfied in an abbreviated fashion by reviewing and completing the administrative data only on the first page of the HRPP audit tool.
- v. **Studies receiving a CSP SMART audit within the previous three years.** RCO audits are audits **conducted, supervised, or verified** by the facility's lead RCO. If a human research study has received an audit by the Cooperative Studies Program (CSP) Site Monitoring and Auditing Review Team (SMART) within the past 3 years, the RCO does not have to perform a separate HRPP audit of the protocol; any audit element not collected in the SMART audit still needs to be checked and collected by the RCO. The RCO should continue to track the study to ensure subsequent HRPP audits are completed if required. The effective date of the audit would be the date of the SMART audit and the next HRPP audit (if required) must be no later than 3 years from the date of the SMART audit. The RCO may always elect to perform an independent HRPP regulatory audit in addition to the SMART audit.

Examples:

- i. A human research study is initially approved by the IRB on June 15, 2019 and by the R&DC on June 25, 2019. The initial HRPP audit must be performed no later than June 24, 2022. The RCO auditor elected to perform an initial HRPP audit on December 12, 2019, soon after subjects begin enrolling. Another HRPP audit is therefore required to be performed no later than December 11, 2022 (3 years from the date of audit). If the IRB closes the study prior to December 11, 2022, no further HRPP audit is required. If the study remains open but subsequent to the HRPP audit the IRB determines that the study is in data analysis or long-term follow up only, no further HRPP regulatory audits would be required, no matter how many years the IRB continued to review the study in data analysis or long-term follow up only.

- ii. A human research study is initially approved by the IRB on February 8, 2020 and by the R&DC on February 15, 2020. The study is **completed** on March 1, 2022. If not performed during a previous reporting period, an HRPP regulatory audit must be performed in time to be included in the (July) 2022 Facility Director Certification of Research Oversight.
 - e. **Deadline.** HRPP audits for the reporting period must be completed in time to be included in the 2022 Facility Director Certification of Research Oversight, which will have to be submitted to ORO no later than the determined deadline. The deadline for the 2022 Facility Director Certification will be no earlier than July 15, 2022.
5. **Regulatory audits required for animal research overseen by the IACUC using ORO's Animal Welfare audit tool.**
- a. All active animal research studies overseen by the IACUC must be audited using ORO's Animal Welfare audit tool (or equivalent) within 3 years of initial IACUC approval or within 3 years of each IACUC triennial review. The audit should include review of the approved protocol submitted at the most recent triennial review as well as IACUC actions and reported events occurring since the most recent triennial review. RCO auditors are allowed to add additional audit elements to ORO's Animal Welfare audit tool and to reformat the data collection instrument, as long as audits include at a minimum all required information on the ORO Animal Welfare audit tool.
 - b. **Records Reviewed** An Animal Welfare regulatory audit includes a review of the IACUC protocol file and research personnel training records, and other research records as needed.
 - c. **Animal Welfare audit plan or SOP** Each facility must have an audit plan or standard operating procedure (SOP) that describes the RCO's auditing process, including Animal Welfare regulatory audits. The SOP or auditing plan should address the source records that may need to be reviewed for Animal Welfare auditing purposes and the roles of the RCO, the PI, and others in the auditing process. The plan or SOP should describe how animal research studies are prioritized for auditing, how Animal Welfare audits are scheduled and executed, how progress towards accomplishing all required audits is monitored, procedures for soliciting study investigators' responses to preliminary audit findings, and how the results of all Animal Welfare audits, are reported to the IACUC and the R&DC as required by VHA Directive 1058.01, including timelines. It is also good practice to describe the RCO's audit record format(s) (electronic and/or hard copies), the locations where RCO records are maintained, and how security of records is assured.
- It is a good practice for the auditor to examine the estimated numbers of animal research studies that will require Animal Welfare regulatory audits at the beginning of the audit period, in order to plan a monthly schedule to accomplish auditing requirements.
- d. **Abbreviated Animal Welfare audits.** If an approved VA animal research study is closed or expires without any animal research activities being initiated, then the requirement for an Animal Welfare audit may be satisfied in an abbreviated fashion by reviewing and completing the administrative data only on the first page of the Animal Welfare audit tool.
 - e. **Closure audits are not required after an initial Animal Welfare audit.** Closure audits are not required for animal studies that have been audited at least once in the last 3 years. This is true

even if the previous Animal Welfare regulatory audit occurred prior to the most recent triennial review.

Examples:

- i. The IACUC initially approves a new animal research protocol on July 15, 2019. The R&DC approves it as VA research on July 25, 2019. The IACUC must perform a triennial review no later than July 14, 2022. Therefore, the RCO must audit this study with the Animal Welfare audit tool (or equivalent) before July 14, 2022. (For planning animal research audits, the important date is not the R&DC approval date or the date of the previous audit, but rather the date of the most recent approval or triennial review by the IACUC.) If the RCO audits the animal protocol on March 15, 2020 and then the IACUC does a triennial review on July 10, 2022, the next RCO animal welfare audit must be completed before July 9, 2025. If the research is completed before July 9, 2019, no additional animal welfare regulatory audit is required.
- ii. A large project overseen by both the IACUC and the IRB received a regulatory audit for its animal research component on July 2, 2019, and a regulatory audit for its human research component on July 9, 2019. Another animal welfare audit must be performed within 3 years of the date of the next IACUC triennial review of the animal research component. If the animal research becomes **completed** before its next triennial review, no additional regulatory audits for the project's animal research are required. An additional regulatory audit for the project's human research is required on or before July 8, 2022.
- f. **Deadline.** Animal Welfare regulatory audits for the reporting period must be completed in time to be included in the 2022 Facility Director Certification of Research Oversight, which will have to be submitted to ORO no later than the determined deadline. The deadline for the 2022 Facility Director Certification will be no earlier than July 15, 2022.

6. **Regulatory audits required for research overseen by the SRS using ORO's Research Safety audit tool.**

Research studies overseen and reviewed annually by the SRS must have a regulatory audit with ORO's Research Safety audit tool (or equivalent) at least every 3 years (i.e., triennially). Initial audit with the SRS tool must be no later than 3 years from initial approval as VA research by the R&D Committee. Except for certain animal research studies (see below), subsequent audits with the SRS tool must be completed no later than 3 years from the previous SRS audit.

VA research followed by the SRS generally falls into one or more of 3 categories: 1) Animal research also followed by the SRS, 2) certain human subjects research that involves exposure to blood or body fluids, human tissues, or other hazards (unless such research solely involves the collection and analysis of biospecimens by VA personnel within clinical areas and/or the performance of standard clinical procedures in clinical areas), or 3) bench or laboratory research that involves hazards or safety concerns. For animal research that is also followed by the SRS the RCO auditor may elect to perform the Research Safety audits in combination with the Animal Welfare audits. These SRS audits may maintain the same schedule, within 3 years of each triennial IACUC review, even if this occasionally results in more than 3 years between the dates of consecutive Animal Welfare/Research Safety audits. All other research overseen by the SRS should have Research

Safety audits no less frequently than every 3 years, whether the Research Safety audits are combined with an HRPP audit or separate.

- a. The Research Safety audit should include a review of the approved protocol, VA Form 10-0398 (when required), and the identified hazards and safety concerns, as well as SRS actions and reported events occurring since study initiation or the previous audit. RCO auditors are allowed to add additional audit elements to ORO's Research Safety audit tool and to reformat the data collection instrument and/or combine it with the HRPP or Animal Welfare tool, as long as audits include at a minimum all required information on the ORO Research Safety audit tool. When performing a Research Safety regulatory audit in combination with an HRPP or Animal Welfare regulatory audit for the same study, it is NOT necessary to record the same information (e.g., research staff training) on both audit tools.
- b. **Records Reviewed** A Research Safety audit includes a review of the SRS protocol file, identified study hazards and safety concerns, specialized required training, if any, research personnel training records, and may include other research records as needed.
- c. **Research Safety Audit Plan or SOP** Each facility must have a standard operating procedure (SOP) that describes the RCO's auditing process, including Research Safety regulatory audits. The SOP or auditing plan should address the source records that may need to be reviewed for Research Safety auditing purposes and the roles of the RCO, the PI, and others in the audit process. The plan or SOP should describe how VA research studies followed by the SRS are prioritized for auditing, how Research Safety audits are scheduled and executed, how progress towards accomplishing all required audits is monitored, procedures for soliciting study investigators' responses to preliminary audit findings, and how the results of all Research Safety audits are reported to the SRS and R&DC as required by VHA Directive 1058.01, including timelines. It is also good practice to describe the RCO's audit record format(s) (electronic and/or hard copies), the locations where RCO records are maintained, and how security of records is assured.

It is a good practice for the auditor to examine the estimated numbers of studies followed by the SRS that will require Research Safety regulatory audits at the beginning of the audit period, in order to plan a monthly schedule to accomplish auditing requirement.

- d. **Abbreviated Research Safety audits.** If a VA study approved by the SRS in accordance with local policies is closed or expires without any research activities involving hazards being initiated, then the requirement for a Research Safety audit may be satisfied in an abbreviated fashion by reviewing and completing the administrative data only on the first page of the Research Safety audit tool.
- e. **Closure audits are not required after an initial Research Safety audit.** Closure audits are not required for studies that have been audited with the research safety tool at least once in the previous 3 years.
- f. **Research followed by the SRS but initiated (i.e., approved for implementation by the R&DC as a VA study) prior to January 1, 2008 does NOT require a Research Safety regulatory audit.**
- g. **Deadline:** Research Safety regulatory audits for the reporting period must be completed in time to be included in the 2022 Facility Director Certification of Research Oversight, which will have

to be submitted to ORO no later than the determined deadline. The deadline for the 2022 Facility Director Certification will be no earlier than July 15, 2022.

7. **Where to find the audit tools and the Facility Director's Certification.**

- a. The RCO audit tools for the June 1, 2021 - May 31, 2022 reporting period will be posted on the RCO section of the ORO SharePoint site and the ORO website.
- b. The 2022 Facility Director's Certification will cover the June 1, 2021 – May 31, 2022 reporting period.
- c. The 2022 Facility Director's Certification with instructions for completion will be posted on the ORO Research Compliance and Technical Assistance SharePoint site and the ORO website no later than June 1, 2022.
- d. The Facility Director Certification will be submitted electronically to ORO. Instructions for submission of the Certification will be sent to every Facility Director.
- e. The ORO website can be found at: <http://www.va.gov/oro/>.
- f. The RCO section of the ORO SharePoint site can be found at:
<https://dvagov.sharepoint.com/sites/VACOVHAORO/RCO/default.aspx>

8. **RCO training requirements.** In addition to conducting required audits, the RCO may serve as a non-voting consultant, as needed, to the facility's R&D Committee, IRB, IACUC, SRS, and other research review committees. The RCO may not serve as a voting or non-voting member of these committees. RCOs must complete and maintain the same training requirements of voting members of the R&DC, the IRB, the IACUC, and the SRS.

For questions related to RCO audit or training requirements, please contact OROPE@VA.GOV.